K073203

510(k) Summary of Safety and Effectiveness

NOV 29 2007

NOV 19 2007

Date:
November 9, 2007

Submitter:
GE Medical Systems *Information Technologies*
4502 Woodland Corporation Boulevard
Tampa, FL 33614 USA

Contact Person:
Karen Russell
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 503-831-3176
Fax: 503-907-8591
E-mail: Karen.Russell@med.ge.com

Secondary Contact Person:
Sharon Untz
Senior Director, Global Quality and Regulatory Affairs Systems
GE Medical Systems *Information Technologies*
Phone: (414) 362-2436
Fax: (414) 362-2585
E-mail: Sharon.Untz@med.ge.com

Device Trade Name:
CARESCAPE V100 Vital Signs Monitor

Common /Usual Name:
Physiological or Vital Signs Monitor, Patient Monitor

Classification Names:
Patient Physiological Monitor (without Arrhythmia Detection)

System, Measurement, Blood Pressure, Noninvasive

Computer, Blood Pressure

Alarm, Blood Pressure

Oximeter

Oximeter, Ear

Thermometer, Clinical Electronic

Recorder, Paper Chart

Predicate Devices:
DINAMAP® ProCare Series 100N-400N Monitor (K022193)

DINAMAP® Pro 1000 Monitor with SuperSTAT (K022834)

Datex-Ohmeda TruSat Pulse Oximeter and Accessories (K040831)

Device Description:
The CARESCAPE V100 Vital Signs Monitor is a small, portable monitor for use in a sub-acute hospital and non-hospital settings. The CARESCAPE V100 is for use on adult, pediatric, or neonatal patients -

one at a time. The battery operated monitor provides noninvasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure, pulse rate, oxygen saturation, and temperature.

The CARESCAPE V100 is a multi-parameter device that provides Sp02 monitoring for use in spot-checking or continuous monitoring. The CARESCAPE V100 also measures NIBP using the oscillometric method. There are no features of CARESCAPE V100 that can be controlled by the patient.

The CARESCAPE V100 monitor is available in four standard configurations with or without an integrated printer:

- CARESCAPE V100 with NIBP (Classic, Classic Auscultatory, or SuperSTAT), Pulse
- CARESCAPE V100 with NIBP (Classic, Classic Auscultatory, or SuperSTAT), Pulse, and Temperature
- CARESCAPE V100 with NIBP (Classic, Classic Auscultatory, or SuperSTAT), Pulse, and Sp02 (Ohmeda TruSignal, Nellcor, or Masimo)
- CARESCAPE V100 with NIBP (Classic, Classic Auscultatory, or SuperSTAT), Pulse, Temperature, and Sp02 (Ohmeda TruSignal, Nellcor, or Masimo)

Intended Use:

The CARESCAPE V100 Vital Signs Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The CARESCAPE V100 Vital Signs Monitor can also be used in satellite areas, physicians' office, or alternate care settings.

Technology:

The CARESCAPE V100 Vital Signs Monitor employs the same functional scientific technology as its predicate device(s).

Test Summary:

The subject of this 510(k) is a design modification for the ProCare V1 Vital Signs Monitor. The CARESCAPE V100 Vital Signs Monitor complies with the voluntary standards as detailed in Section 4.2 of this submission. The following quality assurance measures were applied to the development of the CARESCAPE V100 Vital Signs Monitor:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Subsystem Verification
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the CARESCAPE V100 Vital Signs Monitor is as safe, as effective, and performs as well as the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

GE Medical Systems Information Technologies
c/o Ms. Karen Russell
Regulatory Affairs Specialist
4502 Woodland Corporate Blvd.
Tampa, FL 33614

Re: K073203
Trade Name: CARESCAPE™ V100 Vital Signs Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Code: MHX
Dated: November 9, 2007
Received: November 14, 2007

Dear Ms. Russell:

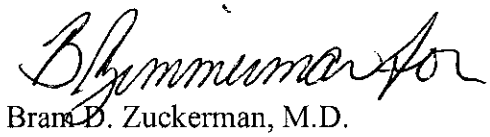
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073203

Device Name: CARESCAPE V100 Vital Signs Monitor

Indications for Use:

The CARESCAPE V100 Vital Signs Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature.

The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The CARESCAPE V100 Vital Signs Monitor can also be used in satellite areas, physicians' office, or alternate care settings.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073203